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NOTICE OF ALLOWANCE AND FEE(S) DUE

4743 7590 10/31/2008 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER

CHICAGO, IL 60606

| EXAMINER | | | | | |
|------------------------|--------------|--|--|--|--|
| GOLDBERG, JEANINE ANNE | | | | | |
| ART UNIT | PAPER NUMBER | | | | |
| 1634 | | | | | |
| DATE MAILED: 10/31/20 | 008 | | | | |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|-------------|----------------------|---------------------|------------------|--|
| 10/829,674 | 04/22/2004 | Anna Helgadottir | 30847/2048-004 | 6838 | |
| TITLE OF INVENTION: SUSCEPTIBILITY GENE FOR MYOCARDIAL INFARCTION AND STROKE | | | | | |

 APPLN TYPE
 SMALL ENTITY
 ISSUE FEE DUE
 PUBLICATION FEE DUE
 PREV. PAID ISSUE FEE
 TOTAL FEE(S) DUE
 DATE DUE

 nonprovisional
 NO
 \$1510
 \$300
 \$0
 \$1810
 02/02/2099

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

| appropriate. All further indicated unless corrects maintenance fee notifica | ed below or directed oth | ng the Patent, advance of nerwise in Block 1, by (| orders and notification a) specifying a new o | of n | naintenance fees w pondence address; | ill be and/or | mailed to the current (b) indicating a sepa | com | espondence address as "FEE ADDRESS" for |
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| CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) | | | | Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. | | | | | |
| 4743 | 7590 10/31 | /2008 | | | Com | tificate | of Mailing on Trans | missi | ion |
| 233 S. WACKE SEARS TOWER | | | | I her State addr trans | eby certify that the es Postal Service we essed to the Mail mitted to the USP | is Fee(ith sul Stop FO (57 | s) Transmittal is being ficient postage for firs ISSUE FEE address I) 273-2885, on the d | dep st cla abov ate ir | osited with the United ss mail in an envelope re, or being facsimile idicated below. |
| CHICAGO, IL 6 | 50606 | | | | | | | | (Depositor's name) |
| | | | | | | | | | (Signature) |
| | | | | $ldsymbol{le}}}}}}$ | | | | | (Date) |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVEN | TOR | | ATTO | RNEY DOCKET NO. | CC | ONFIRMATION NO. |
| 10/829,674 | 04/22/2004 | | Anna Helgadottii | г | | 3 | 0847/2048-004 | | 6838 |
| TITLE OF INVENTION | : SUSCEPTIBILITY GE | ENE FOR MYOCARDIA | AL INFARCTION AN | DST | ROKE | | | | |
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| nonprovisional | NO | \$1510 | \$300 | _ | \$0 | | \$1810 | | 02/02/2009 |
| EXAM | IINER | ART UNIT | CLASS-SUBCLASS | S | | | | | |
| GOLDBERG, JI | | I634 | 435-006000 | | | | | | |
| 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.863). Change of correspondence address (or Change of Correspondence Address form PTOVSB/123) tatached. Change of correspondence address (or Change of Correspondence Address Tem PTOVSB/123) tatached. PTOVSB/17, Rev 09-02 or more recent) attached. Use of a Casiomer PTOVSB/17, Rev 09-02 or more recent) attached. Use of a Casiomer | | 2. For printing on the pattern front page, list (1) the names of up to 3 registered pattent attorneys or agents OR, alternatively, (2) the name of a single firm fluxing as a member a registered attorney or agent) and the names of up to 2 registered pattern attorneys or agents. If no name is 3 | | | | | | | |
| Number is required. | | | listed, no name wi | ill be | printed. | | | | |
| 3. ASSIGNEE NAME A PLEASE NOTE: Uni recordation as set fort (A) NAME OF ASSIG | less an assignee is ident h in 37 CFR 3.11. Comp | A TO BE PRINTED ON ified below, no assignee pletion of this form is NO | | the pa | ntent. If an assignation | | | ocum | nent has been filed for |
| Please check the appropr | iate assignee category or | categories (will not be p | rinted on the patent): | | Individual 🚨 Co | rporati | on or other private gro | oup e | ntity Government |
| 4a. The following fee(s) are submitted: Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies | | | b. Payment of Fee(s): A check is enclose Payment by credition The Director is he overpayment, to be | sed. it care | i. Form PTO-2038 | is atta | ched. required fee(s), any de | ficie | |
| 5. Change in Entity Sta | tus (from status indicate is SMALL ENTITY statu | | □ h Applicant is no | o lone | nor alaiming SMAT | LEN | ITTY status. See 37 Cl | CD 1 | 27(a)(2) |
| NOTE: The Issue Fee an interest as shown by the | | | | | | | | | |
| Authorized Signature | | | | | Date | | | | |
| Typed or printed name | | | | Registration N | o | | | | |
| This collection of inform an application. Confiden submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223 | nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC 113-1450. | CFR 1.311. The informati U.S.C. 122 and 37 CFR USPTO. Time will var- rden, should be sent to to D NOT SEND FEES OR | on is required to obtain 1.14. This collection is depending upon the ne Chief Information C COMPLETED FORM | n or n is est indiv Office IS TO | etain a benefit by the imated to take 12 r idual case. Any co r, U.S. Patent and D'THIS ADDRESS | ne pub ninute: mmen Trader | tic which is to file (and to complete, including s on the amount of tin nark Office, U.S. Depo D TO: Commissioner | i by i ig gar ne ye artme for P | the USPTO to process) thering, preparing, and ou require to complete ent of Commerce, P.O. atents, P.O. Box 1450, |

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| 4743 7 | 590 10/31/2008 | | EXAM | INER | |
| MARSHALL, GERSTEIN & BORUN LLP | | | GOLDBERG, JEANINE ANNE | | |
| 233 S. WACKÉR DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606 | | | ART UNIT | PAPER NUMBER | |
| | | | 1634 DATE MAILED: 10/31/2008 | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

| Application No. | Applicant(s) | | | | |
|--------------------|-------------------|--|--|--|--|
| 10/829,674 | HELGADOTTIR, ANNA | | | | |
| Examiner | Art Unit | | | | |
| JEANINE A GOLDBERG | 1634 | | | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-All claims being allowable, PROSECUTION ON THE MERTIS IS (OR REMAINS) CLOSED in this application. If not included
herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative
of the Office or upon petition by the applicant. See 37 CFR 133 and MPEP 1308.

- 1. This communication is responsive to 7/7/08.
- The allowed claim(s) is/are 61,62,65 and 66.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 - 1.

 Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____
 - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) 🔲 including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) Thereto or 2) to Paper No./Mail Date
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2.
 Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO/SB/08),
- Paper No./Mail Date 8/05; 4/05
- Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date .
- 7. Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- 9. 🔲 Other ___

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DETAILED ACTION

Withdrawal of Restriction Requirement between an allowable subcombination and dependant combination.

1. The restriction requirement between the subcombination haplotype of Claim 61 and the combination haplotype of Claim 62 has been withdrawn in view of the allowability of Claim 61. As provided in the MPEP, where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance.

The claims are drawn to a method of assessing susceptibility to MI in a human subject by screening the nucleic acid for four particular alleles in the FLAP gene. The presence of the haplotype (HapA) identifies the individual as having an elevated

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Art Unit: 1634

susceptibility to MI and the absence of the haplotype identifies the individual as not having the elevated susceptibility to MI due to the haplotype.

The declaration filed by Gudmar Thorleifsson on July 7, 2008 clarifies the record and the differences in values previously presented in the two other declarations and the interview. Given the large meta-analysis and the explanation, the preponderance of the evidence on the record supports the enablement of an association between HapA and MI in human individuals.

- 3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
- 4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

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/Jeanine Goldberg/ Primary Examiner October 31, 2008